Exposing Corruption Exploring Solutions
Project On Government Oversight

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References:

Docket FDA-2002-D-0094-0007. *Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers; Availability*. 2 pages. Posted on the *Federal Register* on April 22, 2010.

Draft Guidance. *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers*. On the first page: "This guidance document is being distributed for comment purposes only." 15 pages. March 2010.

THE FINANCES OF FDA ADVISORY COMMITTEE MEMBERS: IF INFORMATION MUST BE WITHHELD, LET IT BE DONE OPENLY

The review of Avandia: Present disclosure policies are not strong enough

Avandia, a drug made by GlaxoSmithKline for the treatment of diabetes, has been at the center of controversy for years, long before last month's meeting of an FDA Advisory Committee charged with making recommendations on the marketing and labeling of this drug. The long-standing controversy was compounded by a problem that emerged soon after the meeting.

Two of the committee members, David Capuzzi and Abraham Thomas, had received payments from drug companies with a stake in the outcome of the Advisory Committee meeting. The payments may have created a conflict of interest in their review of Avandia for the FDA. Each committee member said he had told the FDA about this financial relationship. However, FDA did not make the information public. Instead, the relationship was revealed after the meeting by the *Wall Street Journal* (first for one member and then the other).

After the meeting a committee member, Arthur Moss, said he wished the FDA had disclosed that Dr. Capuzzi had been a paid speaker for GlaxoSmithKline. "I'm surprised we weren't told," said Moss, according to the *Journal*, which also quoted Arthur Caplan, a medical ethicist not serving on the Advisory Committee. Caplan cited the intense controversy over Avandia: "In the middle of a firestorm over a drug, all connections to the company involved should be disclosed."

Even if the possible conflicts had been publicly disclosed in a timely fashion before the meeting, the recommendations and votes of the committee's members might well have been unaffected. Several members indicated that a pre-meeting disclosure of the conflicts would have made no difference in their own evaluations or in the outcome of the meeting as a whole. But billions of dollars are at stake for drugs like Avandia, and experts' judgment is known to be swayed sometimes by money. Thus there is good reason to aim for maximum disclosure of the private finances of all Advisory Committee members before they meet. The doubts created by the conflicts of interest noticed after the Avandia meeting are at the very least a distraction to the FDA officials who will soon be making decisions on the marketing and labeling of this controversial drug.

A week after the meeting, the chairman of an Advisory Committee that had reviewed Avandia previously (his committee had met in 2007) wrote a Commentary in the *New England Journal of Medicine*. He compared the review three years ago with the latest one:

> A remarkable change has occurred at the FDA that may mean that a final decision about rosiglitazone [Avandia] is near. Since 2007, the agency has become more open in its deliberations, held advisory committee meetings more frequently, and clarified its position on conflicts of interest.

The FDA has done much more than clarify its position on conflicts – it has improved its position considerably. But the improvements haven't gone far enough, as shown by the possible conflicts that turned up after the Avandia review meeting.

The basis for the present system of disclosure: Put your trust in the FDA

Committee members' financial information is routinely withheld from the public at present and will continue to be withheld if the Draft Guidance now being considered at the FDA becomes policy. (See the two documents referenced at the start of this commentary.) Under current practices and those described in the Draft Guidance, financial information is obtained by the FDA from all committee members, but it is withheld from the public at each step:

- Each Advisory Committee member (as well as each candidate for membership at the meeting) files a financial report with the FDA – the Confidential Financial Disclosure Report (CFD report) on Form FDA 3410. The public does not have access to this report for individual committee members, nor do the other members of the Advisory Committee.

- The FDA, following its guidelines, examines the CFD report for possible financial conflicts related to the particular matter before the Advisory Committee.

- The FDA may deem that a committee member ***has no such conflicts***. In that case, the FDA approves the participation of the member in the meeting. For most members of most Advisory Committees, this is what happens. In all these cases, the information in the CFD report remains confidential.

- On the other hand, the FDA may deem that a committee member ***has potential conflicts***. In that case, there are two possibilities. The FDA may decide to exclude this person from the committee meeting (and then the information in the CFD report remains confidential). Alternatively, the FDA may decide that the person is allowed to participate in the meeting (as a voting or non-voting member), despite the potential conflicts. In that case the FDA prepares a waiver explaining its reasons for allowing the person to participate. The FDA publicly releases the waiver, signed by the committee member. The waiver includes certain information in the CFD report, but not all of it.

Most of the information in the CFD reports is never disclosed. Thus certain past and current financial arrangements of Advisory Committee members are known in detail to FDA officials, but most of the details are not disclosed publicly.

This means that members of the public, the press, or Congress who are concerned about conflicts of interest cannot easily verify whether FDA officials have acted reasonably in choosing committee members and granting waivers. Everyone outside the FDA must trust the good faith and good judgment of FDA officials on matters that, in the past, have shown that at least their judgment was sometimes faulty.

An improvement: Trust but verify

Commissioner Margaret Hamburg and other FDA leaders are well aware of this problem and have made good progress in dealing with it. The Draft Guidance (Docket FDA-2002-D-0094-0007) is a step forward, but it's not a big enough step. The guidance, if finalized, will leave too much financial information undisclosed. The result is bound to be occasional Advisory Committee meetings tainted by problems more damaging than those that emerged after the Avandia meeting.

A partial solution, recommended here, is the public release of a photocopy of the actual CFD report (Form FDA 3410), suitably redacted if necessary:

- Each prospective member of an FDA Advisory Committee should be asked to authorize the public release of all the information on Form FDA 3410, with certain exceptions. The exceptions should be much narrower than at present and should be modeled on the disclosures of personal finances required by law for members of Congress and their staff.[1]

[1] There is also a trend toward greater disclosure in medical journals. Fourteen authorities on medical publications, including 12 editors of leading medical journals, announced, in January 2010, some new and tightened requirements for financial disclosure by authors of articles submitted for publication.

- For each member of an Advisory Committee, a copy of Form FDA 3410 should be posted online. As an example, see the photocopies of personal financial disclosure statements posted for members of Congress at OpenSecrets and for members and their staff at LegiStorm.

- If the FDA deems certain information unreleasable, that information should be redacted in a such a way that both the redaction and the reason for the redaction are apparent to viewers in each instance.[2]

I recommend that these requirements for disclosure be applied in the future to the members of Advisory Committees.

Previous comments of mine, submitted in 2007 in response to FDA Draft Guidance, Docket No. 2007D-0101, were similar to those above. Some of the same passages were used in both submissions.

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[2] The basis for each redaction should be shown by means of the exemption codes for the Freedom of Information Act. (Exemption (b)(4), for example, covers trade secrets.) There is no FOIA exemption for personal privacy unless disclosure would constitute a "clearly unwarranted invasion of personal privacy." A candidate committee member can of course withdraw from participation in a committee meeting if he or she wants to avoid the release of personal financial information.